

for any and all urinary proteins from other species.” Applicants respectfully traverse the rejection, and offer the following remarks in support of the allowability of the presently pending claims.

The present invention provides a method of detecting a rodent infestation at a low level before it reaches a higher level of significance. Detection at a low level of infestation prevents the dangers that are concomitant with a high level of infestation, such as for example, transmitted diseases, destruction of materials such as wall and roof insulation, and spoilage of food items. The invention provides a method with which a low-level infestation is detected by testing for one or more proteins that are known to be abundant in rodent urine. The term of art given to this general characteristic of rodents is “obligate proteinuria.”

It is recognized that a patent need not teach, and preferably omits, what is well known in the art. MPEP § 2164.01. “The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” United States v. Telectronics, Inc., 857 F.2d 778, 785 (Fed. Cir. 1988).

Here, the inventors disclose that the present invention was based on their “knowledge of the phenomenon of obligate proteinuria in rodents,” as indicated in the specification at page 3, lines 8-9. Indeed, the inventors stated that they were inspired by this known fact to “investigate whether or not proteins from rodent urine could be used as a basis for testing for rodent infestation.” (Page 3, lines 9-10). Thus, one of skill in the art would know that, as a class, rodents display obligate proteinuria. Taken in light of the examples presented in the specification, the person of skill in the art would realize that a number of other proteins, found in the same or other rodents, may also be detected for the purposes of detecting a rodent infestation. According to MPEP § 2164.01 and the Federal Circuit in Telectronics, the Applicant need not have recited each and every protein that is abundant in rodent urine because such proteins are known to one of skill in the art. The present application is enabled because one of skill in the art could have combined his knowledge of the art with Applicant’s disclosure to practice the disclosed invention without undue experimentation.

Accordingly, the inventors have recited, at page 5, lines 19-23 of the specification, that species of rodents other than mice and rats may express different urinary proteins, and that such proteins may be detected by the methods of the present invention. The inventors even offer examples of other proteins that may be found in the urine of rodents, such as serum albumin and urinary pepsinogen. Thus, one of skill in the art could combine his knowledge of rodent urinary proteins with the inventors' disclosure and follow the recited methods to raise an antibody to other rodent urinary proteins. Methods of raising antibodies to rodent urinary proteins are recited in the specification at pages 10-13 and are well within the purview of one of skill in the art.

Therefore, although the inventors did not provide working examples for all rodents, the disclosures in the patent coupled with information known in the art clearly teaches how to use the recited methods to detect infestation by any number of rodents, through the presence of urinary proteins characteristically found in rodents.

The enablement standard does not require the Applicants to demonstrate that the claimed invention in fact works; actual reduction to practice is not necessary prior to filing. Gould v. Quigg, 822 F.2d 1074, 1078 (Fed. Cir. 1987); MPEP § 2164.02. "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claims, then the enablement requirement of 35 U.S.C. § 112 is satisfied." In re Fisher, 427 F.2d 833, 839 (CCPA 1970); MPEP § 2164.01(b). Applicants have recited detailed methodology for practicing the claimed invention and have provided disclosure to support their claims to the detection of urinary proteins from rodents, rather than simply specific proteins from mice and rats. Applicants have provided detailed examples of the working of their invention in mice and rats and have disclosed that their invention could be easily practiced by one of skill in the art with respect to other proteins and other species. Thus, according to the Fisher court, Applicants' disclosure bears a reasonable correlation to the scope of the claims and the enablement standard has been satisfied.

Applicants respectfully point out that, even though they have provided working examples of their invention, compliance with the enablement requirement of 35 U.S.C. § 112 does not require the disclosure of working examples. As noted above, actual reduction to practice is not required for an application to be enabled. Accordingly, the

Gould court held that “[t]he mere fact that something has not been previously done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it. Gould, 822 F.2d 1078; MPEP § 2164.02. Thus, the lack of working examples cannot be used as an independent basis for rejecting a claim on enablement grounds; indeed, an invention is enabled if it is otherwise disclosed in a manner allowing one skilled in the art to practice it without undue experimentation. In re Borkowski, 422 F.2d 904, 908 (CCPA 1970); MPEP § 2164.02. In the instant application, a lack of working examples for all rodents should not form a basis for rejection because, as shown above, one of skill in the art would know that the phenomenon of obligate proteinuria is found in all rodents and, thus, would know how to combine his knowledge with Applicants’ disclosure to practice the claimed invention with respect to other urinary proteins and other rodent species.

Here, the specification clearly discloses that the claimed methods may be practiced by detecting the presence of one or more proteins present in the urine of rodents in accordance with the known phenomenon of obligate proteinuria. Merely by way of example, pages 3-5 of the specification fully describe exemplary types of rodent proteins that may be used with the claimed method, and describes on pages 7-8 the types of substratum that can be used to pick up the proteins. On pages 6-7 of the specification, common types of assays and associated antibodies that may be used to detect the exemplary proteins are described. The specification also includes a detailed description of a specific example in relation to using the method to detect mice infestation (Example, pages 10-16). The Example provides further disclosure by teaching the exact measurements, materials, and steps that were used by the inventors themselves to show that the method was successful in detecting mice infestation. Thus, Applicants have actually exceeded the requirements of 35 U.S.C. § 112 by providing *actual* examples that succeeded, even though Applicants respectfully maintain that working examples are not necessary for the enablement of the presently claimed invention.

Furthermore, mice and rats are merely representative of rodents, as are Major Urinary Proteins and  $\alpha$ 2u globulins urinary proteins representative of characteristic proteins in rodent urinary samples. Thus, while Applicants have chosen to provide a specific example of the inventive method using Major Urinary Proteins and  $\alpha$ 2u globulins

urinary proteins to detect mice and rats (Example, page 10-17), their choice to present one embodiment in greater detail than others does not defeat the fact that the application is enabled for detecting urinary proteins of rodents as a class. Thus, claims 12-22 are, necessarily, enabled.

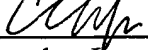
In sum, the present application constitutes more than a mere invitation to experiment. Considerable guidance is provided such that one skilled in the art could easily practice the methods recited in claims 12-22. Such a conclusion is supported by the actual examples provided and by the cited passages of the specification.

Applicants believe that the currently pending claims are in a condition for allowance, and a favorable action is respectfully requested. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles telephone number (213) 488-7100 to discuss the steps necessary for placing the application in condition for allowance, should the Examiner believe that such a telephone conference would advance prosecution of the application.

Respectfully submitted,

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Date: June 8, 2005

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## Addendum

1. PILLSBURY WINTHROP SHAW PITTMAN LLP